A guide to VANFLYTA®

Distribution and Support Services

Important Safety Information

WARNING: QT PROLONGATION, TORSADES DE POINTES, and CARDIAC ARREST

- **VANFLYTA® (quizartinib) prolongs the QT interval in a dose- and concentration-related manner. Prior to VANFLYTA administration and periodically, monitor for hypokalemia or hypomagnesemia, and correct deficiencies. Perform electrocardiograms (ECGs) to monitor the QTc at baseline, weekly during induction and consolidation therapy, weekly for at least the first month of maintenance, and periodically thereafter.**
- **Torsades de pointes and cardiac arrest have occurred in patients receiving VANFLYTA. Do not administer VANFLYTA to patients with severe hypokalemia, severe hypomagnesemia, or long QT syndrome.**
- **Do not initiate treatment with VANFLYTA or escalate the VANFLYTA dose if the QT interval corrected by Fridericia's formula (QTcF) is greater than 450 ms.**
- **Monitor ECGs more frequently if concomitant use of drugs known to prolong the QT interval is required.**
- **Reduce the VANFLYTA dose when used concomitantly with strong CYP3A inhibitors, as they may increase quizartinib exposure.**
- **Because of the risk of QT prolongation, VANFLYTA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the VANFLYTA REMS.**

Indication

VANFLYTA is indicated in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 internal tandem duplication (ITD)–positive as detected by an FDA-approved test.

Limitations of Use:

VANFLYTA is not indicated as maintenance monotherapy following allogeneic hematopoietic stem cell transplantation (HSCT); improvement in overall survival with VANFLYTA in this setting has not been demonstrated.

Please see Important Safety Information throughout, and click the following links for Full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

VANFLYTA®
quizartinib tablets
26.5 mg | 17.7 mg

Helping your patients access VANFLYTA

Your patients and your practice are important to us

Daiichi Sankyo, Inc. is committed to helping appropriate patients get access to VANFLYTA by providing access and reimbursement support.

OFFERING SUPPORT ALONG THE WAY

Coverage and access support

- **Benefit investigation and claims assistance:** Expert help from reimbursement specialists
- **Billing and coding information:** Important information related to VANFLYTA reimbursement
- **VANFLYTA QuickStart Program:** Patients experiencing a coverage delay greater than 5 business days may be eligible to receive a 14-day supply at no cost (up to 1 refill)

Financial assistance

- **VANFLYTA Savings Program:** Copay savings may help reduce commercially insured patients' out-of-pocket costs
- **Patient Assistance Program:** Help for eligible uninsured, underinsured, or Medicare enrollees who are unable to meet their out-of-pocket costs

CONTACT DAIICHI SANKYO ACCESS CENTRAL

Phone:
1-866-4-DSI-NOW (1-866-437-4669)

Available Monday – Friday,*
8:00 AM – 6:00 PM ET

*Excludes holidays.

Website:
DSIAccessCentral.com

Important Safety Information (cont'd)

Contraindications

VANFLYTA is contraindicated in patients with severe hypokalemia, severe hypomagnesemia, long QT syndrome, or in patients with a history of ventricular arrhythmias or torsades de pointes.

Please see Important Safety Information throughout, and click the following links for Full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

Overview: Filling VANFLYTA prescriptions

VANFLYTA is available through network specialty pharmacies, as well as office- or hospital-based pharmacies

Prescribers who use a network specialty pharmacy will submit prescriptions to the specialty pharmacy directly, and the pharmacy will ship the medication to patients.

Prescribers will need to contact the specialty pharmacy directly regarding prescriptions and patient support services.

Please see page 3 for more information.

If using an office-, hospital-, or health system-based pharmacy that is Risk Evaluation and Mitigation Strategy (REMS) certified, such pharmacy may order from one of seven specialty distributors for subsequent dispensing.

Prescribers who utilize an office-, hospital-, or health system-based pharmacy may contact **Daiichi Sankyo Access Central** regarding patient support services.

Regardless of pharmacy type utilized, complete a Patient Enrollment Form to initiate an assessment of your patient's eligibility for VANFLYTA support programs.

Click below to download the Patient Enrollment Form
www.DSIAccessCentral.com/hcp/vanflyta/resources

VANFLYTA REMS

VANFLYTA is available only through a restricted distribution program under a REMS called the VANFLYTA REMS because of the serious risk of QT prolongation, torsades de pointes, and cardiac arrest. Notable requirements of the VANFLYTA REMS include the following:

- Prescribers must be certified in the VANFLYTA REMS by enrolling in and completing training
- Prescribers must counsel patients receiving VANFLYTA about the risk of QT prolongation, torsades de pointes, and cardiac arrest, and provide patients with a Patient Wallet Card
- Pharmacies that dispense VANFLYTA must be certified with the VANFLYTA REMS and must verify prescribers are certified through the VANFLYTA REMS

Enrollment in the VANFLYTA REMS is available at **www.VANFLYTAREMS.com**

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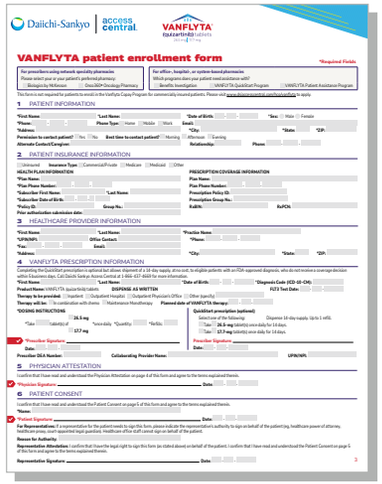
Using a network specialty pharmacy

When using a network specialty pharmacy to fill a prescription, please fax the Patient Enrollment Form to the specialty pharmacy. This will allow the specialty pharmacy to:

- Conduct a benefits investigation
- Provide guidance on prior authorization (PA) submissions
- Assist with enrollment into the VANFLYTA Savings Program for eligible, commercially-insured patients
- Refer eligible uninsured or commercially-underinsured patients to the VANFLYTA Patient Assistance Program
- Conduct research on alternative financial assistance for commercially-insured patients, if necessary, such as searches through independent third-party foundations
- Fill the prescription* upon confirmation of coverage and prescriber REMS certification


VANFLYTA patient enrollment form

Patient Enrollment Form

*Network specialty pharmacies will accept prescriptions filled out via the Patient Enrollment Form, as well as traditional prescriptions sent separately from the Patient Enrollment Form.

Click below to download the Patient Enrollment Form
WWW.DSIACCESSCENTRAL.COM/HCP/VANFLYTA/RESOURCES

Network specialty pharmacy contact information

Biologics by McKesson

Phone:
1-800-850-4306

Fax:
1-800-823-4506

Onco360® Oncology Pharmacy

Phone:
1-877-662-6633

Fax:
1-877-662-6355

Daiichi Sankyo does not represent Biologics, Onco360, or any specialty pharmacy.

REMEMBER TO COMPLETE A PATIENT ENROLLMENT FORM to allow your patient's eligibility for VANFLYTA support programs to be assessed

Important Safety Information (cont'd)

Warnings and Precautions

QT Prolongation, Torsades de Pointes, and Cardiac Arrest (See BOXED WARNING)
VANFLYTA prolongs the QT interval in a dose- and concentration-dependent manner. The mechanism of QTc interval prolongation is via inhibition of the slow delayed rectifier potassium current, I_{Ks}, as compared to all other medications that prolong the QTc interval, which is via the rapid delayed rectifier potassium current, I_{Kr}.

Therefore, the level of QTc prolongation with VANFLYTA that predicts the risk of cardiac arrhythmias is unclear. Inhibition of I_{Ks} and I_{Kr} may leave patients with limited reserve, leading to a higher risk of QT prolongation and serious cardiac arrhythmias, including fatal outcomes.

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Using an office-, hospital-, or health system-based pharmacy

When your office-, hospital-, or health system-based pharmacy is filling the prescription, VANFLYTA can be ordered through one of the following specialty distributors:

ASD

Phone: 1-800-746-6273

Fax: 1-800-547-9413

Website: www.asdhealthcare.com

Cardinal Health Specialty Distribution

Phone: 1-866-677-4844

Website: specialtyonline.cardinalhealth.com

Cardinal Health Puerto Rico

Phone: 1-787-625-4200

Fax: 1-787-625-4398

Website: orderexpress.cardinalhealth.com

McKesson Plasma and Biologics

Phone: 1-877-625-2566

Fax: 1-888-752-7626

Website: www.mckesson.com/pharmaceutical-distribution/plasma-biologics/

McKesson Specialty Health

Phone: 1-855-477-9800

Fax: 1-800-800-5673

Website: www.mckessonspecialtyhealth.com

Morris & Dickson Specialty Distribution

Phone: 1-318-798-5295

Fax: 1-318-524-3096

Website: https://www.morrisdickson.com/products/specialty/

Oncology Supply

Phone: 1-800-633-7555

Fax: 1-800-248-8205

Website: www.oncologysupply.com

REMEMBER TO COMPLETE A PATIENT ENROLLMENT FORM to allow your patient's eligibility for VANFLYTA support programs to be assessed

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

Torsades de pointes, ventricular fibrillation, cardiac arrest, and sudden death have occurred in patients treated with VANFLYTA.

Of the 1,081 patients with AML treated with VANFLYTA in clinical trials, torsades de pointes occurred in approximately 0.2% of patients, cardiac arrest occurred in 0.6% of patients, including 0.4% with a fatal outcome, and 0.1% of patients experienced ventricular fibrillation. These severe cardiac arrhythmias occurred predominantly during the induction phase.

Of the 265 patients with newly diagnosed FLT3-ITD–positive AML treated with VANFLYTA in combination with chemotherapy in the clinical trial, 2.3% were found to have a QTcF greater than 500 ms and 10% of patients had an increase from baseline QTcF greater than 60 ms. The clinical trial excluded patients with a QTcF ≥450 ms or other factors that increased the risk of QT prolongation or arrhythmic events (eg, NYHA Class III or IV congestive heart failure, hypokalemia, family history of long QT interval syndrome).

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Considerations when submitting a PA

The patient and healthcare provider are responsible for completing and submitting coverage- and reimbursement-related documentation.

- **VANFLYTA dosing can vary according to treatment stage**
  - Some insurers may require authorization for each dose strength
- **The VANFLYTA indication statement and prescribing information** may be requested
- **Supporting clinical rationale**, including peer-reviewed literature and compendia listings, may be necessary
- **Relevant medical history and prognosis** will likely be required, including:
  - Test results documenting FLT3-ITD+ disease
  - Baseline lab results and ECG readings
  - Prior AML therapies that the patient has received, if applicable
  - Treatment goals
- **Applicable ICD-10-CM codes** may be required
  - Relevant procedure and place-of-service codes may also be required

Click below to download helpful resources, including a sample letter of medical necessity
WWW.DSIACCESSCENTRAL.COM/HCP/VANFLYTA/RESOURCES

Daiichi Sanko Access Central coordinators are available to assist you and can be reached at
1-866-4-DSI-NOW (1-866-437-4669),
Monday through Friday, 8:00 AM - 6:00 PM ET

Important codes

Product Information

Tablet strength	Packaging configuration	Color	NDC	Debossing
17.7 mg (equivalent to 20 mg quizartinib dihydrochloride)	Bottle of 28		65597-504-28	DSC511
	Bottle of 14		65597-504-04	
26.5 mg (equivalent to 30 mg quizartinib dihydrochloride)	Bottle of 28		65597-511-28	DSC512
	Bottle of 14		65597-511-04	

Tablets shown are not actual size.

Possible Diagnosis Codes for AML (ICD-10-CM)

Code	Description
C92.00	Acute myeloblastic leukemia, not having achieved remission
C92.50	Acute myelomonocytic leukemia, not having achieved remission
C92.60	Acute myeloid leukemia with 11q23-abnormality, not having achieved remission
C92.A0	Acute myeloid leukemia with multilineage dysplasia, not having achieved remission
C93.00	Acute monoblastic-monocytic leukemia, not having achieved remission

This table is provided for informational purposes only. Healthcare providers have the responsibility to ensure claims and codes submitted are accurate, complete, and applicable. Coding and documentation are the responsibility of the provider and should be confirmed with each payer.

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

Therefore, avoid use in patients who are at significant risk of developing torsades de pointes, including uncontrolled or significant cardiac disease, recent myocardial infarction, heart failure, unstable angina, bradyarrhythmias, tachyarrhythmias, uncontrolled hypertension, high-degree atrioventricular block, severe aortic stenosis, or uncontrolled hypothyroidism.

Please see Important Safety Information throughout, and click the following links for Full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

Abbreviations: AML, acute myeloid leukemia; HSCT, hematopoietic stem cell transplantation; ICD-10-CM, International Classification of Disease, Tenth Revision, Clinical Modification; ITD, internal tandem duplication; NDC, National Drug Code.

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Daiichi Sankyo Access Central

Daiichi Sankyo Access Central provides access and financial support to patients who have been prescribed VANFLYTA

VANFLYTA Savings Program

Commercially-insured patients may pay as little as $0 per prescription with a maximum benefit of $26,000 per calendar year

- No income requirements
- Patients participating in federal healthcare programs—including but not limited to Medicare, Medicaid, TRICARE, and Veterans Affairs—are not eligible

VANFLYTA Patient Assistance Program

May provide drug at no cost for eligible patients who are uninsured, underinsured, or Medicare enrollees

VANFLYTA QuickStart Program

Provides eligible patients with a 14-day supply at no cost (up to 1 refill)

- Patients must be experiencing a coverage delay greater than 5 business days after submission of a completed PA

Click below to download the Patient Enrollment Form
WWW.DSIACCESSCENTRAL.COM/HCP/VANFLYTA/RESOURCES

Daiichi-Sankyo | access central™

A single source for support

Contact information

Website:
www.DSIAccessCentral.com/hcp/vanflyta

Phone:
1-866-4-DSI-NOW (1-866-437-4669)

Fax:
1-833-374-0884

VISIT THE DAIICHI SANKYO ACCESS CENTRAL WEBSITE or **CALL AN ACCESS CENTRAL COORDINATOR** for more information on any of our support programs

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

Do not initiate treatment with VANFLYTA if the QTcF interval is greater than 450 ms. Do not use VANFLYTA in patients with severe hypokalemia, severe hypomagnesemia, long QT syndrome, or in patients with a history of ventricular arrhythmias or torsades de pointes. Perform an ECG and correct electrolyte abnormalities prior to initiation of treatment with VANFLYTA.

During induction and consolidation, perform an ECG prior to initiation and then once weekly during VANFLYTA treatment or more frequently as clinically indicated. During maintenance, perform ECGs prior to initiation, once weekly for at least the first month following dose initiation and escalation, and as clinically indicated thereafter.

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Important Safety Information

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Indication

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Limitations of Use:

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Contraindications

VANFLYTA is contraindicated in patients with severe hypokalemia, severe hypomagnesemia, long QT syndrome, or in patients with a history of ventricular arrhythmias or torsades de pointes.

Warnings and Precautions

QT Prolongation, Torsades de Pointes, and Cardiac Arrest (See BOXED WARNING)

VANFLYTA prolongs the QT interval in a dose- and concentration-dependent manner. The mechanism of QTc interval prolongation is via inhibition of the slow delayed rectifier potassium current, I_{Ks}, as compared to all other medications that prolong the QTc interval, which is via the rapid delayed rectifier potassium current, I_{Kr}.

Therefore, the level of QTc prolongation with VANFLYTA that predicts the risk of cardiac arrhythmias is unclear. Inhibition of I_{Ks} and I_{Kr} may leave patients with limited reserve, leading to a higher risk of QT prolongation and serious cardiac arrhythmias, including fatal outcomes. Torsades de pointes, ventricular fibrillation, cardiac arrest, and sudden death have occurred in patients treated with VANFLYTA.

Of the 1,081 patients with AML treated with VANFLYTA in clinical trials, torsades de pointes occurred in approximately 0.2% of patients, cardiac arrest occurred in 0.6% of patients, including 0.4% with a fatal outcome, and 0.1% of patients experienced ventricular fibrillation. These severe cardiac arrhythmias occurred predominantly during the induction phase.

Of the 265 patients with newly diagnosed FLT3-ITD–positive AML treated with VANFLYTA in combination with chemotherapy in the clinical trial, 2.3% were found to have a QTcF greater than 500 ms and 10% of patients had an increase from baseline QTcF greater than 60 ms. The clinical trial excluded patients with a QTcF ≥450 ms or other factors that increased the risk of QT prolongation or arrhythmic events (eg, NYHA Class III or IV congestive heart failure, hypokalemia, family history of long QT interval syndrome).

Therefore, avoid use in patients who are at significant risk of developing torsades de pointes, including uncontrolled or significant cardiac disease, recent myocardial infarction, heart failure, unstable angina, bradyarrhythmias, tachyarrhythmias, uncontrolled hypertension, high-degree atrioventricular block, severe aortic stenosis, or uncontrolled hypothyroidism.

Do not initiate treatment with VANFLYTA if the QTcF interval is greater than 450 ms. Do not use VANFLYTA in patients with severe hypokalemia, severe hypomagnesemia, long QT syndrome, or in patients with a history of ventricular arrhythmias or torsades de pointes. Perform an ECG and correct electrolyte abnormalities prior to initiation of treatment with VANFLYTA.

During induction and consolidation, perform an ECG prior to initiation and then once weekly during VANFLYTA treatment or more frequently as clinically indicated. During maintenance, perform ECGs prior to initiation, once weekly for at least the first month following dose initiation and escalation, and as clinically indicated thereafter.

Do not escalate the dose if QTcF is greater than 450 ms. Perform ECG monitoring of the QT interval more frequently in patients who are at significant risk of developing QT interval prolongation and torsades de pointes, or following dose escalation.

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Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

Monitor and correct hypokalemia and hypomagnesemia prior to and during treatment with VANFLYTA. Maintain electrolytes in the normal range. Monitor electrolytes and ECGs more frequently in patients who experience diarrhea or vomiting. Monitor patients more frequently with ECGs if coadministration of VANFLYTA with drugs known to prolong the QT interval is required.

Reduce the VANFLYTA dose when used concomitantly with strong CYP3A inhibitors, as they may increase quizartinib exposure. Reduce VANFLYTA if QTc increases to greater than 480 ms and less than 500 ms. Interrupt and reduce VANFLYTA if QTc increases to greater than 500 ms. Permanently discontinue VANFLYTA in patients who develop recurrent QTc greater than 500 ms or QTc interval prolongation with signs or symptoms of life-threatening arrhythmia. VANFLYTA is available only through a restricted program under a REMS.

VANFLYTA REMS

VANFLYTA is available only through a restricted distribution program under a REMS called the VANFLYTA REMS because of the serious risk of QT prolongation, torsades de pointes, and cardiac arrest.

Notable requirements of the VANFLYTA REMS include the following:

- Prescribers must be certified in the VANFLYTA REMS by enrolling and completing training.
- Prescribers must counsel patients receiving VANFLYTA about the risk of QT prolongation, torsades de pointes, and cardiac arrest, and provide patients with a Patient Wallet Card.
- Pharmacies that dispense VANFLYTA must be certified with the VANFLYTA REMS and must verify prescribers are certified through the VANFLYTA REMS.

Further information about the VANFLYTA REMS is available at www.VANFLYTAREMS.com or by telephone at 1-855-212-6670.

Embryo-Fetal Toxicity

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with VANFLYTA and for 7 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with VANFLYTA and for 4 months after the last dose.

Adverse Reactions

The safety of VANFLYTA (35.4 mg orally once daily with chemotherapy, 26.5 mg to 53 mg orally once daily as maintenance) in adult patients with newly diagnosed FLT3-ITD positive AML is based on QuANTUM-First.

Serious adverse reactions in ≥5% of patients who received VANFLYTA plus chemotherapy were: febrile neutropenia (11%). Fatal adverse reactions occurred in 10% of patients who received VANFLYTA plus chemotherapy, including sepsis (5%), fungal infections (0.8%), brain edema (0.8%), and one case each of febrile neutropenia, pneumonia, cerebral infarction, acute respiratory distress syndrome, pulmonary embolism, ventricular dysfunction, and cardiac arrest.

Permanent discontinuation due to an adverse reaction in patients in the VANFLYTA plus chemotherapy arm occurred in 20% of patients. The most frequent (≥2%) adverse reaction which resulted in permanent discontinuation in the VANFLYTA arm was sepsis (5%).

Dosage interruptions of VANFLYTA due to an adverse reaction occurred in 34% of patients. Adverse reactions which required dosage interruption in ≥2% of patients in the VANFLYTA arm included neutropenia (11%), thrombocytopenia (5%), and myelosuppression (3%).

Dose reductions of VANFLYTA due to an adverse reaction occurred in 19% of patients. Adverse reactions which required dosage reductions in ≥2% of patients in the VANFLYTA arm were neutropenia (9%), thrombocytopenia (5%), and electrocardiogram QT prolonged (4%).

The most common adverse reactions (≥10% with a difference between arms of ≥2% compared to placebo), including laboratory abnormalities, were decreased lymphocytes, decreased potassium, decreased albumin, decreased phosphorus, increased alkaline phosphatase, decreased magnesium, febrile neutropenia, diarrhea, mucositis, nausea, decreased calcium, abdominal pain, sepsis, neutropenia, headache, increased creatine phosphokinase, vomiting, upper respiratory tract infections, hypertransaminasemia, thrombocytopenia, decreased appetite, fungal infections, epistaxis, increased potassium, herpesvirus infections, insomnia, QT prolongation, increased magnesium, increased sodium, dyspepsia, anemia, and eye irritation.

Drug Interactions

Strong CYP3A Inhibitors

VANFLYTA is a CYP3A substrate. Concomitant use of VANFLYTA with a strong CYP3A inhibitor increases quizartinib systemic exposure, which may increase the risk of VANFLYTA adverse reactions. Reduce the dosage of VANFLYTA.

Strong or Moderate CYP3A Inducers

Concomitant use of VANFLYTA with strong or moderate CYP3A inducers decreases quizartinib systemic exposure, which may reduce VANFLYTA efficacy. Avoid concomitant use of VANFLYTA with strong or moderate CYP3A inducers.

QT Interval–Prolonging Drugs

VANFLYTA prolongs the QT/QTc interval. Coadministration of VANFLYTA with other drugs that prolong the QT interval may further increase the incidence of QT prolongation. Monitor patients more frequently with ECG if coadministration of VANFLYTA with drugs known to prolong the QT interval is required.

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Important Safety Information (cont'd)

Use in Specific Populations

Pregnancy
VANFLYTA can cause embryo-fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus.

Lactation
Advise women not to breastfeed during treatment with VANFLYTA and for one month after the last dose.

Females and Males of Reproductive Potential

Pregnancy Testing
Verify pregnancy status in females of reproductive potential within 7 days before starting treatment with VANFLYTA.

Contraception

Females
Advise female patients of reproductive potential to use effective contraception during treatment with VANFLYTA and for 7 months after the last dose.

Males
Advise male patients with female partners of reproductive potential to use effective contraception during treatment with VANFLYTA and for 4 months after the last dose.

Infertility

Females
Based on findings from animal studies, VANFLYTA may impair female fertility. These effects on fertility were reversible.

Males
Based on findings from animal studies, VANFLYTA may impair male fertility. These effects on fertility were reversible.

Pediatric Use
Safety and effectiveness of VANFLYTA have not been established in pediatric patients.

Geriatric Use
No overall differences in safety or efficacy were observed between patients 65 years of age and older and younger adult patients.

Renal Impairment
No dosage adjustment is recommended in patients with mild to moderate renal impairment (CLcr 30 to 89 mL/min). VANFLYTA has not been studied in patients with severe renal impairment (CLcr <30 mL/min).

Hepatic Impairment
No dosage adjustment is recommended in patients with mild hepatic impairment or moderate hepatic impairment. VANFLYTA has not been studied in patients with severe hepatic impairment.

To report SUSPECTED ADVERSE REACTIONS, contact Daiichi Sankyo, Inc, at 1-877-437-7763 or the FDA at 1-800-FDA-1088 or fda.gov/medwatch.

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